(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 November 2005 (24.11.2005)

PCT

(10) International Publication Number
WO 2005/110244 A1

(51) International Patent Classification[7]: A61B 17/04

(21) International Application Number:
PCT/US2005/015765

(22) International Filing Date: 6 May 2005 (06.05.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

10/841,411	7 May 2004 (07.05.2004)	US
10/840,951	7 May 2004 (07.05.2004)	US
10/840,950	7 May 2004 (07.05.2004)	US
10/841,245	7 May 2004 (07.05.2004)	US
10/869,472	15 June 2004 (15.06.2004)	US
11/036,866	14 January 2005 (14.01.2005)	US

(71) Applicant (*for all designated States except US*): **USGI MEDICAL INC.** [US/US]; 1140 Calle Cordillera, San Clemente, CA 92673 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **SAADAT, Vahid** [US/US]; 12679 Kane Drive, Saratoga, CA 95070 (US). **MAAHS, Tracy, D.** [US/US]; 11 Paseo Simpatico, Rancho Santa Margarita, CA 92688 (US). **EWERS, Richard, C.** [US/US]; 1437 West Malvern, Fullerton, CA 92833 (US). **ELMER, Marvin, C.** [US/US]; 68 Tiera Segura, Rancho Santa Margarita, CA 92688 (US). **FLORES, Jesus** [US/US]; 319 Chochise Road, Perris, CA 92570 (US). **KHAIRKHAHAN, Alex** [US/US]; 1105 Lincoln Avenue, Palo Alto, CA 94301 (US). **PEH, Ruey-Feng** [SG/US]; 555 East El Camino Real #707, Sunnyvale, CA 94087 (US). **LAM, Cang, C.** [US/US]; 74 Stanford Court, Irvine, CA 92612 (US).

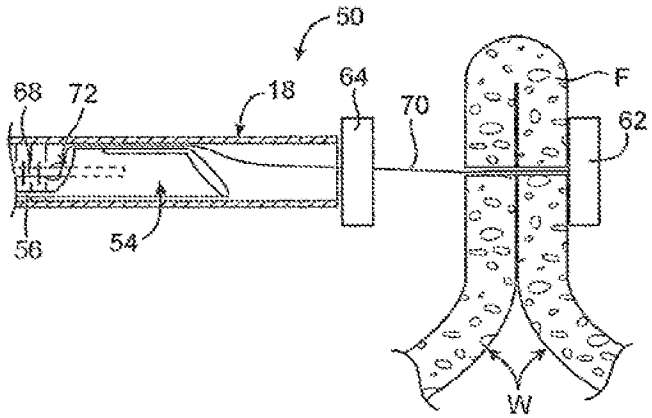
(74) Agents: **HESLIN, James, M.** et al.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th Floor, San Francisco, California 94111-3834 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,

[Continued on next page]

(54) Title: APPARATUS AND METHODS FOR POSITIONING AND SECURING ANCHORS



(57) Abstract: Apparatus and methods for positioning and securing anchors are disclosed herein. The anchors are adapted to be delivered and implanted into or upon tissue, particularly tissue within the gastrointestinal system of a patient. The anchor is adapted to slide uni-directionally over suture such that a tissue plication may be cinched between anchors. A locking mechanism either within the anchor itself of positioned proximally of the anchor may allow for the uni-directional translation while enabling the anchor to be locked onto the suture if the anchor is pulled, pushed, or otherwise urged in the opposite direction along the suture. This uni-directional anchor locking mechanism facilitates the cinching of the tissue plication between the anchors and it may be utilized in one or several anchors in cinching a tissue fold.

WO 2005/110244 A1

ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

APPARATUS AND METHODS FOR POSITIONING AND SECURING ANCHORS

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This is a continuation-in-part application of U.S. Pat. App. Serial Nos. 10/840,950 (Attorney docket no. 021496-000900 US); 10/841,245 (Attorney docket no. 021496-001000 US); 10/840,951 (Attorney docket no. 021496-001100 US); and 10/841,411 (Attorney docket no. 021496-001200 US), each of which was filed May 7, 2004. This present application is also a continuation-in-part of U.S. Pat. App. Serial Nos. 10/869,472 (Attorney docket no. 021496-000910 US), filed on June 15, 2004 and 11/036,866 (Attorney docket no. 021496-000940 US), filed January 14, 2005, each of which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] Field of the Invention. The present invention relates to apparatus and methods for positioning and securing anchors within tissue. More particularly, the present invention relates to apparatus and methods for positioning and securing anchors within folds of tissue within a body.

[0003] Morbid obesity is a serious medical condition pervasive in the United States and other countries. Its complications include hypertension, diabetes, coronary artery disease, stroke, congestive heart failure, multiple orthopedic problems and pulmonary insufficiency with markedly decreased life expectancy.

[0004] A number of surgical techniques have been developed to treat morbid obesity, e.g., bypassing an absorptive surface of the small intestine, or reducing the stomach size. However, many conventional surgical procedures may present numerous life-threatening post-operative complications, and may cause atypical diarrhea, electrolytic imbalance, unpredictable weight loss and reflux of nutritious chyme proximal to the site of the anastomosis.

[0005] Furthermore, the sutures or staples that are often used in these surgical procedures typically require extensive training by the clinician to achieve competent use, and may concentrate significant force over a small surface area of the tissue, thereby potentially

causing the suture or staple to tear through the tissue. Many of the surgical procedures require regions of tissue within the body to be approximated towards one another and reliably secured. The gastrointestinal lumen includes four tissue layers, wherein the mucosa layer is the inner-most tissue layer followed by connective tissue, the muscularis layer and the serosa layer.

[0006] One problem with conventional gastrointestinal reduction systems is that the anchors (or staples) should engage at least the muscularis tissue layer in order to provide a proper foundation. In other words, the mucosa and connective tissue layers typically are not strong enough to sustain the tensile loads imposed by normal movement of the stomach wall during ingestion and processing of food. In particular, these layers tend to stretch elastically rather than firmly hold the anchors (or staples) in position, and accordingly, the more rigid muscularis and/or serosa layer should ideally be engaged. This problem of capturing the muscularis or serosa layers becomes particularly acute where it is desired to place an anchor or other apparatus transesophageally rather than intraoperatively, since care must be taken in piercing the tough stomach wall not to inadvertently puncture adjacent tissue or organs.

[0007] One conventional method for securing anchors within a body lumen to the tissue is to utilize sewing devices to suture the stomach wall into folds. This procedure typically involves advancing a sewing instrument through the working channel of an endoscope and into the stomach and against the stomach wall tissue. The contacted tissue is then typically drawn into the sewing instrument where one or more sutures or tags are implanted to hold the suctioned tissue in a folded condition known as a plication. Another method involves manually creating sutures for securing the plication.

[0008] One of the problems associated with these types of procedures is the time and number of intubations needed to perform the various procedures endoscopically. Another problem is the time required to complete a plication from the surrounding tissue with the body lumen. In the period of time that a patient is anesthetized, procedures such as for the treatment of morbid obesity or for GERD must be performed to completion. Accordingly, the placement and securement of the tissue plication should ideally be relatively quick and performed with a minimal level of confidence.

[0009] Another problem with conventional methods involves ensuring that the staple, knotted suture, or clip is secured tightly against the tissue and that the newly created plication will not relax under any slack which may be created by slipping staples, knots, or clips.

Other conventional tissue securement devices such as suture anchors, twist ties, crimps, etc. are also often used to prevent sutures from slipping through tissue. However, many of these types of devices are typically large and unsuitable for low-profile delivery through the body, e.g., transesophageally.

[0010] Moreover, when grasping or clamping onto or upon the layers of tissue with conventional anchors, sutures, staples, clips, etc., may of these devices are configured to be placed only after the tissue has been plicated and not during the actual plication procedure.

BRIEF SUMMARY OF THE INVENTION

[0011] In securing plications which may be created within a body lumen of a patient, various methods and devices may be implemented. Generally, any number of conventional methods may be utilized for initially creating the plication. One method in particular may involve creating a plication through which a tissue anchor may be disposed within or through. A distal tip of a tissue plication apparatus may engage or grasp the tissue and move the engaged tissue to a proximal position relative to the tip of the device, thereby providing a substantially uniform plication of predetermined size. Examples of tools and methods which are particularly suited for delivering the anchoring and securement devices may be seen in further detail in co-pending U.S. Pat. App. Serial No. 10/735,030 filed December 12, 2003, which is incorporated herein by reference in its entirety.

[0012] In securing these plications, various tissue anchors may be utilized for securing the plications in their configured folds. For example, a plication (or plications) may be secured via a length or lengths of suture extending through the plication and between a distally-positioned tissue anchor located on a distal side of the plication and a proximally-positioned tissue anchor located on a proximal side of the plication. Examples of anchors which may be utilized are disclosed in co-pending U.S. Pat. App. Serial No. 10/612,170, filed July 1, 2003, which is incorporated herein by reference in its entirety.

[0013] Generally, in securing a tissue plication, a proximally and/or distally located tissue anchor is preferably configured to slide along the connecting suture in a uni-directional manner. For instance, if the proximal anchor is to be slid along the suture, it is preferably configured to translate over the suture such that the tissue plication is cinched between the anchors. In this example, the proximal anchor is preferably configured to utilize a locking mechanism which allows for the free uni-directional translation of the suture therethrough

while enabling the anchor to be locked onto the suture if the anchor is pulled, pushed, or otherwise urged in the opposite direction along the suture. This uni-directional anchor locking mechanism facilitates the cinching of the tissue plication between the anchors and it may be utilized in one or several of the anchors in cinching a tissue fold.

[0014] Moreover, the types of anchors utilized for the securement of tissue plications are not intended to be limiting. For instance, many of the anchor locking or cinching mechanisms may be utilized with, e.g., "T"-type anchors as well as with reconfigurable "basket"-type anchors, which generally comprise a number of configurable struts or legs extending between at least two collars or support members. Other variations of these or other types of anchors are also contemplated for use in an anchor locking or cinching assembly.

[0015] For instance, linear anchors, i.e., elongate anchors which are configured to fold or become compressed into a bowed or expanded configuration, may also be utilized. Such anchors may be configured in a variety of different configurations, such as flattened ribbon or wire, having one or more openings along its length through which a length of suture may be routed. Generally, a linear-type anchor for placement against a tissue surface may comprise an elongate member having a proximal end, a distal end, and a length therebetween defining a plurality of holes, a length of suture for passage through at least one of the holes, and wherein the elongate member is adapted to be reconfigured from a straightened configuration to an expanded anchoring configuration when the elongate member is compressed longitudinally. In utilizing such a linear-type anchor, one method of positioning the anchor against the tissue surface may generally comprise positioning an elongate member in a straightened configuration against the tissue surface, the elongate member having a proximal end, a distal end, and a length therebetween, and compressing the elongate member longitudinally such that the elongate member reconfigures to an expanded anchoring configuration against the tissue surface.

[0016] Furthermore, a single type of anchor may be used exclusively in an anchor locking or cinching assembly; alternatively, a combination of different anchor types each utilizing different anchor locking or cinching mechanisms may be used in a single assembly. Furthermore, the different types of cinching or locking mechanisms are not intended to be limited to any of the particular variations shown and described below but may be utilized in any combinations or varying types of anchors as practicable.

[0017] The suture itself may be modified or altered to integrate features or protrusions along its length or a specified portion of its length. Such features may be defined uniformly at regular intervals along the length of suture or intermittently, depending upon the desired locking or cinching effects. Furthermore, the suture may be made from metals such as Nitinol, stainless steels, Titanium, etc., provided that they are formed suitably thin and flexible. Using metallic sutures with the anchoring mechanisms may decrease any possibilities of suture failure and it may also provide a suture better able to withstand the acidic and basic environment of the gastrointestinal system. Also, it may enhance imaging of the suture and anchor assembly if examined under imaging systems. Sutures incorporating the use of features or protrusions along its length as well as sutures fabricated from metallic materials or any other conventional suture type may be utilized with any of the locking or cinching mechanisms described below in various combinations, if so desired.

[0018] One variation for utilizing a locking mechanism which allows for free uni-directional translation of the suture through the anchor may include blocks or members which are adapted to slide within or upon an anchor to lock the suture. These blocks or members may include tapered edges which act to cleat the suture depending upon the direction the anchor is translated relative to the suture. Moreover, these blocks may be biased or urged to restrict the movement of the suture using a variety of biasing elements, such as springs, etc. In addition to blocks, one or several locking tabs which are levered to allow uni-directional travel of the suture through an anchor may also be utilized.

[0019] Aside from the use of mechanical locking features integrated within or with the anchor bodies, locking mechanisms may also utilize a variety of knotting techniques. Conventional knots, which are typically tied by the practitioner either within the body or outside the body and advanced over the suture length, may be utilized for locking the anchor in place relative to the tissue fold and opposing anchor; however, self-locking knots which enable the uni-directional travel of an anchor body relative to the suture and tissue are desirable. Accordingly, many different types of self-locking knots may be advanced with the anchor over the suture such that translation along a distal direction is possible yet reverse translation of the anchor is inhibited.

[0020] Various anchor cinching or locking mechanisms utilizing friction as a primary source for locking may also be implemented. For instance, locking pins may be urged or pushed into a frictional interference fit with portions or areas of the suture against the anchor

or portions of the anchor. The use of such pins may effectively wedge the suture and thereby prevent further movement of the anchor along the suture length. In addition to pins, locking collars or collets may also be used to cinch or lock the suture.

[0021] In addition to friction-based locking and cinching mechanisms utilizable in tissue anchors, other mechanisms which create tortuous paths for the suture within or through the anchors may also be utilized for creating uni-directional locking. One cinching variation may utilize a pulley or pin contained within the anchor over which a portion of the suture may travel. The looped suture may then be routed proximally and secured with a slip knot. As tension is applied to the suture, the slip knot may prevent the further movement of the anchor relative to the suture.

[0022] Another variation on utilizing tortuous paths may comprise collars which are independent from or integrally formed with the anchors. Such cinching collars may generally be formed into tubular structures having obstructions or interference elements disposed or formed within the collar lumen where the obstructions may, for example, be formed from portions of the cinching collar itself. These obstructions may be adapted to form upon releasing of a constraining force when the anchor is to be locked into position. Alternatively, the interference elements or obstructions may comprise separate elements disposed within the collar lumen, such as one or more balls, spheres, etc. These obstructions or elements may be used to form a tortuous path through which the suture may be routed to lock the suture within.

[0023] Moreover, locking collars which form tortuous paths may be adapted to reconfigure themselves from a constrained delivery configuration to a deployed locking configuration when the anchor is to be cinched or locked into position relative to the tissue and suture. The locking collars may be configured to take various configurations, such as a proximally extending "S"-type, or other types, configuration.

[0024] Other cinching and locking mechanisms which utilize mechanical clamping or crimping to achieve locking of the suture within or through the anchors may also be used to facilitate uni-directional locking. For instance, a simple mechanical crimp may be fastened upon the suture proximally of the anchor to prevent the reverse motion of the anchor. The crimp may be a simple tubular member or it may be integrally formed onto a proximal portion of the anchor body itself.

[0025] Aside from the crimping mechanisms described above, additional measures may be optionally implemented to facilitate the cinching or locking of an anchor. Other measures may also be taken to inhibit any damage from occurring to the suture routed through an anchor. For instance, to ensure that the integrity of the suture is maintained in the presence of metallic basket anchors and to ensure that the suture is not subjected to any nicks or cuts, the portion of the suture passing through basket anchor may be encased in a protective sleeve made, e.g., from polypropylene, PTFE, etc.

[0026] Another measure which may optionally be implemented are cinching or locking mechanisms which take advantage of any cold-flow effects of an engaged portion of suture by the tissue anchor. For instance, if a portion of the suture is wedged against the collar of an anchor or cinching member to lock the anchor, the portion of the collar may have multiple holes defined over its surface to allow for portions of the engaged suture to cold-flow at least partially into or through the holes to enhance the locking effects.

[0027] Alternatively, the collar may be formed with an electrically conductive inner sleeve surrounded by an outer sleeve capable of flowing at least partially when heated. The inner sleeve may have a number of holes defined over its surface such that when the outer sleeve is heated, either by inductive heating or any other method, the outer sleeve material may flow through the holes and into contact with the suture passing therethrough. This contact may also enhance the locking effects of the collar.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] Fig. 1A shows a side view of one variation of a tissue plication apparatus which may be used to create tissue plications and to deliver cinching or locking anchors into the tissue.

[0029] Figs. 1B and 1C show detail side and perspective views, respectively, of the tissue manipulation assembly of the device of Fig. 1A.

[0030] Figs. 2A to 2D show an example of a tissue plication procedure for the delivery and placement of tissue anchors.

[0031] Figs. 3A to 3G show detail cross-sectional views of an anchor delivery assembly in proximity to a tissue plication and an example of delivering the tissue anchors on distal and proximal sides of the plication.

[0032] Figs. 4A and 4B show side and end views, respectively, of one anchor variation which is illustrated in the form of a T-type anchor utilizing locking blocks or members for cinching and locking the suture.

[0033] Fig. 5 shows a side view of another cinching anchor variation utilizing locking blocks or members.

[0034] Fig. 6 shows yet another side view of a cinching anchor variation utilizing locking blocks or members.

[0035] Fig. 7 shows a perspective view of another locking anchor variation in which the anchor body defines an opening having a tapered or grooved portion.

[0036] Figs. 8A and 8B show cross-sectional side and top views, respectively, of another locking anchor variation utilizing a through-hole passage or opening and uni-directional levers or pivots through which the suture may pass.

[0037] Fig. 8C shows a cross-sectional side view of an anchor body in combination with a modified suture having integrated features or protrusions defined along its length.

[0038] Figs. 9A and 9B show cross-sectional views of locking anchor variations having biased locking members in combination with a knotted suture.

[0039] Fig. 9C shows another modification of the suture which may be coated with a metallic covering or slid within a sleeve.

[0040] Fig. 10 shows a cross-sectional side view of an anchor assembly which utilizes a choke-type loop for cinching the anchors uni-directionally towards one another.

[0041] Fig. 11A shows a perspective view of another anchor assembly utilizing a slip knot at the proximal anchor.

[0042] Figs. 11B and 11C show top and cross-sectional side views, respectively, of an anchor which may optionally define grooves or channels extending at least partially therein to facilitate the cinching or wedging of the sutures within the grooves.

[0043] Figs. 12A to 12G show examples of anchor assemblies utilizing various slip knots and looped sections which provide uni-directional travel for the anchors over the sutures.

[0044] Fig. 13A shows a cross-sectional side view of an anchor delivery system delivering a basket-type anchor into or through a tissue plication.

[0045] Fig. 13B shows a cross-sectional side view of multiple tissue plications which may be cinched towards one another and basket anchors as being deliverable through one or both tissue plications.

[0046] Figs. 14A and 14B show cross-sectional side views of an anchor cinching assembly utilizing a cinching collar or collet which may be wedged into an anchor collar for clamping upon the suture.

[0047] Figs. 15A and 15C show cross-sectional side views of another anchor cinching assembly utilizing a pin for wedging against a portion of the suture.

[0048] Figs. 15B and 15D show end views of the assembly of Figs. 15A and 15C, respectively.

[0049] Fig. 15E shows a perspective view of another cinching variation utilizing one or more tapered pins or blocks slidably disposed within a tapered channel defined in a proximal collar of the anchor.

[0050] Fig. 15F shows a perspective view of the tapered pins from Fig. 15E.

[0051] Figs. 15G and 15H show cross-sectional side views of an alternative cinching assembly having a retractable pin in an engaged and disengaged configuration, respectively.

[0052] Figs. 16A and 16B show cross-sectional side views of another variation of a cinching assembly having a rotatable cinching collar.

[0053] Figs. 17A and 17B show cross-sectional side views of another cinching assembly having a retaining tube for providing a counterforce to stabilize the assembly during cinching or locking.

[0054] Figs. 18A and 18B show cross-sectional side views of another cinching assembly having one or several biasing members or cinching tabs.

[0055] Figs. 18C and 18D show end and perspective views, respectively, of a suture release member which may be used with the assembly of Figs. 18A and 18B.

[0056] Figs. 19A and 19B show cross-sectional side views of another variation of a cinching assembly utilizing a deformable cinching member positioned within the anchor and distally of the anchor collar.

[0057] Fig. 20A shows a cross-sectional side view of another cinching assembly utilizing a pivoting cinching member configured to lock against the suture.

[0058] Figs. 20B, 20C, and 20D show end and cross-sectional side views, respectively, of the pivoting member positioned within the anchor collar.

[0059] Figs. 20E and 20F show cross-sectional side and perspective views, respectively, of another cinching assembly having a pivoting cinching member positioned proximally of the anchor collar.

[0060] Figs. 21A and 21B show cross-sectional side views of another cinching assembly configured to cinch or lock the suture with a tapered collar.

[0061] Fig. 22A shows a cross-sectional side view of another cinching assembly utilizing a looped suture and a slip knot for cinching the anchor over the suture.

[0062] Figs. 22B and 22C show cross-sectional side and detail views, respectively, of another cinching assembly which may be utilized with a portion of suture wrapped or looped about a pin which enables uni-directional travel of the anchor relative to the suture

[0063] Figs. 22D and 22E show cross-sectional side and detail views, respectively, of another cinching assembly utilizing looped suture wedged within the anchor collar.

[0064] Fig. 23 shows a cross-sectional side view of a cinching assembly variation utilizing a number of pulleys to create the cinching effect.

[0065] Fig. 24A shows a cross-sectional side view of another cinching assembly variation in which a cinching sleeve may be used to create a tortuous path for the suture.

[0066] Figs. 24B and 24C show cross-sectional side views of another cinching assembly variation having a tubular structure, with and without retaining arms, respectively, positioned within the anchor collar through which the suture may pass uni-directionally.

[0067] Fig. 24D shows a perspective view of one variation of the tubular structure of Fig. 24C with retaining arms.

[0068] Figs. 25A and 25B show cross-sectional side views of another cinching assembly variation in which a cinching collar, which may be independent of the anchor or formed integrally with the anchor, respectively, may have a tortuous path formed within the collar.

[0069] Fig. 25C shows a perspective view of the collar of Fig. 25A in its unobstructed configuration with a constraining sleeve which may be positioned within the collar.

[0070] Figs. 26A and 26B show cross-sectional side views of another cinching assembly variation utilizing one or several pivoting levers which allow uni-directional travel of the suture therethrough.

[0071] Figs. 26C and 26D show alternative end views of the assembly of Fig. 26A in which the lever may be configured to prevent over cinching onto the suture.

[0072] Figs. 26E to 26G show cross-sectional side views of alternative cinching assemblies in which the levers may be variously configured to create the tortuous path.

[0073] Figs. 27A and 27B show side views of another cinching assembly variation in a delivery profile and a reconfigured profile, respectively, which utilizes a crimp which may be self-forming.

[0074] Figs. 28A and 28B show cross-sectional side views of another cinching assembly variation utilizing either two cinching collars or a single integral cinching collar, respectively.

[0075] Fig. 28C shows a cross-sectional side view of the cinching collar of Fig. 28A in one configuration for cinching the suture.

[0076] Figs. 28D and 28E show perspective views of the cinching collar of Fig. 28A in a delivery profile and a reconfigured profile.

[0077] Fig. 28F shows a cross-sectional side view of another variation for a cinching configuration of the cinching collar of Fig. 28B.

[0078] Figs. 28G and 28H show cross-sectional side views of another cinching assembly variation in a delivery profile and reconfigured profile, respectively, in which an elongate cinching member may reconfigure itself to create a tortuous path for the suture.

[0079] Figs. 29A and 29B show cross-sectional side views of another cinching assembly variation utilizing a mechanical crimp.

[0080] Figs. 30A and 30B show cross-sectional side views of another cinching assembly variation in which a mechanical crimp may be utilized on the proximal collar of the anchor body.

[0081] Fig. 31A shows a cross-sectional side view of a variation of a tool assembly which may be adapted to apply a mechanical crimping force upon a crimping collar.

[0082] Figs. 31B to 31D show side, end, and perspective views, respectively, of a variation on a crimping collar which may be utilized as a separate crimping sleeve or as part of the anchor collar.

[0083] Figs. 32A and 32B show cross-sectional side and perspective views, respectively, of an alternative crimping tool.

[0084] Figs. 33A and 33B show perspective and end views, respectively, of a representative basket anchor having a protective sleeve encasing the suture disposed within the anchor.

[0085] Figs. 34A and 34B show cross-sectional side and perspective views, respectively, of a cinching collar defining a plurality of holes through the surface of the collar for enhancing the locking effects with the suture.

[0086] Fig. 35A shows a cross-sectional side view of a cinching assembly variation which may utilize inductive heating to partially melt a portion of an outer sleeve into contact with the suture to enhance the anchor locking effects.

[0087] Figs. 35B and 35C show perspective assembly and exploded views, respectively, of an electrically conductive inner sleeve contained within the outer sleeve.

[0088] Figs. 35D and 35E show perspective views of alternative inner sleeves which may be utilized with the assembly of Fig. 35A.

[0089] Figs. 36A and 36B show perspective views of variations of linear anchors generally comprised of elongate ribbon or flattened wire and defining one or more openings along their lengths.

[0090] Figs. 37A and 37B show the ribbon anchors of Figs. 36A and 36B, respectively, with lengths of suture routed through the openings.

[0091] Fig. 38 shows another variation of a ribbon anchor having alternating portions of the ribbon material between the openings notched out or removed.

[0092] Fig. 39 shows another variation of a ribbon anchor defining undulations such that an "S"-type ribbon pattern is formed.

[0093] Fig. 40A shows the ribbon anchor of Fig. 36A with biasing springs positioned along portions of the ribbon anchor with suture routed therethrough.

[0094] Fig. 40B shows another variation of the ribbon anchor of Fig. 40A having biased ribbon elements rather than springs.

[0095] Fig. 40C shows the ribbon anchor of Fig. 40A in a partially collapsed configuration.

[0096] Fig. 40D shows the ribbon anchor of Fig. 40B in a partially collapsed configuration.

[0097] Fig. 41 shows an alternative variation of the ribbon anchor comprised of a tubular member.

[0098] Fig. 42 shows a perspective view of another alternative variation of the ribbon anchor comprised of a tubular member having a partial cut-out along its length.

[0099] Fig. 43 shows a perspective view of yet another alternative variation of the ribbon anchor having multiple cut-outs along its length.

[0100] Fig. 44 shows a perspective view of yet another alternative having multiple individual lengths of elements encased (or at least partially encased) in a coating or covering.

[0101] Fig. 45 shows a perspective view of yet another alternative having one or more lengths of wire covered or coated.

[0102] Fig. 46 shows another variation in which a length of the ribbon anchor may have a non-uniform thickness.

[0103] Figs. 47A and 47B shows yet other variations in which a length of wire having eyelets or defining loops may be utilized to fold or flatten into an expanded pattern.

[0104] Fig. 48 shows another variation in which a wire or ribbon may be comprised of a shape memory alloy which is configured to form a tangled portion of the wire when unconstrained.

[0105] Figs. 49A and 49B show partial cross-sectional views of ribbon anchors in a flattened linear configuration becoming compressed into a collapsed and expanded configuration, respectively, against a fold of tissue.

[0106] Figs. 50A to 50F show top views of various bowed or expanded configurations of a ribbon anchor.

[0107] Figs. 51A and 51B are side-views, partially in section, of a cinching assembly comprising an interference element.

[0108] Figs. 52A-52C are, respectively, an isometric view, a sectional isometric view and a side-sectional view of the cinching assembly of Figs. 51.

[0109] Figs. 53A-53D are side-views, partially in section, of variations of the cinching assembly of Figs. 51 and 52.

DETAILED DESCRIPTION OF THE INVENTION

[0110] In order to first create the plication within a body lumen of a patient, various methods and devices may be implemented. The anchoring and securement devices may be delivered and positioned via an endoscopic apparatus that engages a tissue wall of the gastrointestinal lumen, creates one or more tissue folds, and disposes one or more of the anchors through the tissue fold(s). The tissue anchor(s) may be disposed through the muscularis and/or serosa layers of the gastrointestinal lumen.

[0111] Generally, in creating a plication through which a tissue anchor may be disposed within or through, a distal tip of a tissue plication apparatus may engage or grasp the tissue and move the engaged tissue to a proximal position relative to the tip of the device, thereby providing a substantially uniform plication of predetermined size.

[0112] Formation of a tissue fold may be accomplished using at least two tissue contact areas that are separated by a linear or curvilinear distance, wherein the separation distance between the tissue contact points affects the length and/or depth of the fold. In operation, a tissue grabbing assembly engages or grasps the tissue wall in its normal state (i.e., non-folded and substantially flat), thus providing a first tissue contact area. The first tissue contact area then is moved to a position proximal of a second tissue contact area to form the tissue fold. The tissue anchor assembly then may be extended across the tissue fold at the second tissue contact area. Optionally, a third tissue contact point may be established such that, upon formation of the tissue fold, the second and third tissue contact areas are disposed on opposing sides of the tissue fold, thereby providing backside stabilization during extension of the anchor assembly across the tissue fold from the second tissue contact area.

[0113] The first tissue contact area may be utilized to engage and then stretch or rotate the tissue wall over the second tissue contact area to form the tissue fold. The tissue fold may then be articulated to a position where a portion of the tissue fold overlies the second tissue

contact area at an orientation that is substantially normal to the tissue fold. A tissue anchor may then be delivered across the tissue fold at or near the second tissue contact area. An apparatus in particular which is particularly suited to deliver the anchoring and securement devices described herein may be seen in further detail in co-pending U.S. Pat. App. Serial No. 10/735,030 filed December 12, 2003 and entitled "Apparatus And Methods For Forming And Securing Gastrointestinal Tissue Folds", which is incorporated herein by reference in its entirety.

[0114] An illustrative side view of a tissue plication assembly **10** which may be utilized with the tissue anchors described herein is shown in Fig. 1A. The plication assembly **10** generally comprises a catheter or tubular body **12** which may be configured to be sufficiently flexible for advancement into a body lumen, e.g., transorally, percutaneously, laparoscopically, etc. Tubular body **12** may be configured to be torqueable through various methods, e.g., utilizing a braided tubular construction, such that when handle **16** is manipulated and rotated by a practitioner from outside the body, the torquing force is transmitted along body **12** such that the distal end of body **12** is rotated in a corresponding manner.

[0115] Tissue manipulation assembly **14** is located at the distal end of tubular body **12** and is generally used to contact and form the tissue plication, as mentioned above. Fig. 1B shows an illustrative detail side view of tissue manipulation assembly **14** which shows launch tube **18** extending from the distal end of body **12** and in-between the arms of upper extension member or bail **20**. Launch tube **18** may define launch tube opening **24** and may be pivotally connected near or at its distal end via hinge or pivot **22** to the distal end of upper bail **20**. Lower extension member or bail **26** may similarly extend from the distal end of body **12** in a longitudinal direction substantially parallel to upper bail **20**. Upper bail **20** and lower bail **26** need not be completely parallel so long as an open space between upper bail **20** and lower bail **26** is sufficiently large enough to accommodate the drawing of several layers of tissue between the two members.

[0116] Upper bail **20** is shown in the figure as an open looped member and lower bail **26** is shown as a solid member; however, this is intended to be merely illustrative and either or both members may be configured as looped or solid members. Tissue acquisition member **28** may be an elongate member, e.g., a wire, hypotube, etc., which terminates at a tissue grasper **30**, in this example a helically-shaped member, configured to be reversibly rotatable for

advancement into the tissue for the purpose of grasping or acquiring a region of tissue to be formed into a plication. Tissue acquisition member **28** may extend distally from handle **16** through body **12** and distally between upper bail **20** and lower bail **26**. Acquisition member **28** may also be translatable and rotatable within body **12** such that tissue grasper **30** is able to translate longitudinally between upper bail **20** and lower bail **26**. To support the longitudinal and rotational movement of acquisition member **28**, an optional guide or sled **32** may be connected to upper **20** or lower bail **26** to freely slide thereon. Guide **32** may also be slidably connected to acquisition member **28** such that the longitudinal motion of acquisition member **28** is supported by guide **32**.

[0117] An example of a tissue plication procedure is seen in Figs. 2A to 2D for delivering and placing a tissue anchor and is disclosed in further detail in co-pending U.S. Pat. App. Serial No. 10/735,030 filed December 12, 2003, which has been incorporated by reference above. Tissue manipulation assembly **14**, as seen in Fig. 2A, may be advanced into a body lumen such as the stomach and positioned adjacent to a region of tissue wall **40** to be plicated. During advancement, launch tube **18** may be configured in a delivery profile such that tube **18** is disposed within or between the arms of upper bail **20** to present a relatively small profile.

[0118] Once tissue manipulation assembly **14** has been desirably positioned relative to tissue wall **40**, tissue acquisition member **30** may be advanced distally such that tissue acquisition member **30** comes into contact with tissue wall **40** at acquisition location or point **42**. As acquisition member **30** is distally advanced relative to body **12**, guide **32**, if utilized, may slide distally along with member **30** to aid in stabilizing the grasper. If a helically-shaped acquisition member **30** is utilized, as illustrated in Fig. 2B, it may be rotated from its proximal end at handle **16** and advanced distally until the tissue at point **42** has been firmly engaged by acquisition member **30**. This may require advancement of acquisition member **30** through the mucosal layer and at least into or through the underlying muscularis layer and preferably into or through the serosa layer.

[0119] The grasped tissue may then be pulled proximally between upper **20** and lower bails **26** via acquisition member **30** such that the acquired tissue is drawn into a tissue fold **44**, as seen in Fig. 2C. As acquisition member **30** is withdrawn proximally relative to body **12**, guide **32** may also slide proximally to aid in stabilizing the device especially when drawing the tissue fold **44**.

[0120] Once the tissue fold **44** has been formed, launch tube **18** may be advanced from its proximal end at handle **16** such that a portion **46** of launch tube **18**, which extends distally from body **12**, is forced to rotate at hinge or pivot **22** and reconfigure itself such portion **46** forms a curved or arcuate shape that positions launch tube opening **24** perpendicularly relative to a longitudinal axis of body **12** and/or bail members **20, 26**. Launch tube **18**, or at least portion **46** of launch tube **18**, is preferably fabricated from a highly flexible material or it may be fabricated, e.g., from Nitinol tubing material which is adapted to flex, e.g., via circumferential slots, to permit bending. Alternatively, assembly **14** may be configured such that launch tube **18** is reconfigured simultaneously with the proximal withdrawal of acquisition member **30** and acquired tissue **44**.

[0121] As discussed above, the tissue wall of a body lumen, such as the stomach, typically comprises an inner mucosal layer, connective tissue, the muscularis layer and the serosa layer. To obtain a durable purchase, e.g., in performing a stomach reduction procedure, the staples or anchors used to achieve reduction of the body lumen are preferably engaged at least through or at the muscularis tissue layer, and more preferably, the serosa layer. Advantageously, stretching of tissue fold **44** between bail members **20, 26** permits an anchor to be ejected through both the muscularis and serosa layers, thus enabling durable gastrointestinal tissue approximation.

[0122] As shown in Fig. 2D, once launch tube opening **24** has been desirably positioned relative to the tissue fold **44**, needle assembly **48** may be advanced through launch tube **18** via manipulation from its proximal end at handle **16** to pierce preferably through a dual serosa layer through tissue fold **44**. Needle assembly **48** is preferably a hollow tubular needle through which one or several tissue anchors may be delivered through and ejected from in securing the tissue fold **44**, as further described below.

[0123] Because needle assembly **48** penetrates the tissue wall twice, it exits within the body lumen, thus reducing the potential for injury to surrounding organs. A detail cross-sectional view is shown in Fig. 3A of anchor delivery assembly **50** in proximity to tissue fold **F**. In this example, tissue fold **F** may comprise a plication of tissue created using the apparatus **10** described herein or any other tool configured to create such a tissue plication. Tissue fold **F** may be disposed within a gastrointestinal lumen, such as the stomach, where tissue wall **W** may define the outer or serosal layer of the stomach. Anchor delivery assembly may generally comprise launch tube **18** and needle assembly **48** slidingly disposed within launch

tube lumen **52**. Needle assembly **48** is generally comprised of needle **54**, which is preferably a hollow needle having a tapered or sharpened distal end **66** to facilitate its travel into and/or through the tissue. Other parts of the assembly, such as upper and lower bail members **20**, **26**, respectively, and tissue acquisition member **28** have been omitted from these figures only for clarity.

[0124] Once launch tube **18** has been desirably positioned with respect to tissue fold **F**, needle **54** may be urged or pushed into or through tissue fold **F** via needle pushrod or member **56** from its proximal end preferably located within handle **16**. Needle **54** may define needle lumen **58** within which distal anchor **62** and/or proximal anchor **64** may be situated during deployment and positioning of the assembly. A single suture or flexible element **70** (or multiple suture elements) may connect proximal anchor **64** and distal anchor **62** to one another. For instance, element **70** may comprise various materials such as monofilament, multifilament, or any other conventional suture material, elastic or elastomeric materials, e.g., rubber, etc.

[0125] Alternatively, metals which are biocompatible may also be utilized for suture materials. For instance, sutures may be made from metals such as Nitinol, stainless steels, Titanium, etc., provided that they are formed suitably thin and flexible. Using metallic sutures with the anchoring mechanisms described herein may additionally provide several benefits. For example, use of metallic suture material may decrease any possibilities of suture failure due to inadvertent cutting or shearing of the suture, it may provide a suture better able to withstand the acidic and basic environment of the gastrointestinal system, and it may also enhance imaging of the suture and anchor assembly if examined under conventional imaging systems such as X-rays, fluoroscopes, MRI, etc. As used herein, suture **70** may encompass any of these materials or any other suitable material which is also biocompatible.

[0126] Needle **54** may optionally define needle slot **60** along its length to allow suture **70** to pass freely within and out of needle **54** when distal anchor **62** is ejected from needle lumen **58**. Alternatively, rather than utilizing needle slot **60**, needle **54** may define a solid structure with suture **70** being passed into needle lumen **58** via the distal opening of needle **54**.

[0127] The proximal end of suture **70** may pass slidingly through proximal anchor **64** to terminate in suture loop **74** via cinching knot **72**. Suture loop **74** may be omitted and the proximal end of suture **70** may terminate proximally of the apparatus **10** within control handle **16**, proximally of control handle **16**, or at some point distally of control handle **16**. In

this variation, suture loop **74** may be provided to allow for a grasping or hooking tool to temporarily hold suture loop **74** for facilitating the cinching of proximal **64** and distal **62** anchors towards one another for retaining a configuration of tissue fold **F**, as described in further detail below. Cinching knot **72** may also comprise a slidable knot which may be slid distally along suture **70** to lock or hold against proximal anchor **64** once the tissue fold **F** and anchors **62, 64** have been desirably positioned and tensioned, as also described below in further detail.

[0128] After needle assembly **48** has been pushed distally out through launch tube opening **24** and penetrated into and/or through tissue fold **F**, as shown in Fig. 3B, anchor pushrod or member **68** may be actuated also via its proximal end to eject distal anchor **62**, as shown in Fig. 3C. Once distal anchor **62** has been ejected distally of tissue fold **F**, Fig. 3D shows how needle **54** may be retracted back through tissue fold **F** by either retracting needle **54** back within launch tube lumen **52** or by withdrawing the entire anchor delivery assembly **50** proximally relative to tissue fold **F**.

[0129] Fig. 3E shows that once needle **54** has been retracted, proximal anchor **64** may then be ejected from launch tube **18** on a proximal side of tissue fold **F**. With both anchors **62, 64** disposed externally of launch tube **18** and suture **70** connecting the two, proximal anchor **64** may be held against the distal end of launch tube **18** and urged into contact against tissue fold **F**, as shown in Figs. 3F and 3G, respectively. As proximal anchor **64** is urged against tissue fold **F**, proximal anchor **64** or a portion of suture **70** may be configured to provide any number of directionally translatable locking mechanisms which provide for movement of an anchor along suture **70** in a first direction and preferably locks, inhibits, or prevents the reverse movement of the anchor back along suture **70**. In other alternatives, the anchors may simply be delivered through various elongate hollow tubular members, e.g., a catheter, trocars, etc.

[0130] With respect to the anchor assemblies described herein, the types of anchors shown and described are intended to be illustrative and are not limited to the variations shown. For instance, several of the tissue anchor variations are shown as "T"-type anchors while other variations are shown as reconfigurable "basket"-type anchors, which may generally comprise a number of configurable struts or legs extending between at least two collars or support members. Other variations of these or other types of anchors are also contemplated for use in an anchor assembly. Examples of anchors which may be utilized are disclosed in co-pending

U.S. Pat. App. Serial No. 10/612,170, filed July 1, 2003, which is incorporated herein by reference in its entirety. Moreover, a single type of anchor may be used exclusively in an anchor assembly; alternatively, a combination of different anchor types may be used in an anchor assembly. Furthermore, the different types of cinching or locking mechanisms are not intended to be limited to any of the particular variations shown and described but may be utilized in any of the combinations or varying types of anchors as practicable.

[0131] To accomplish the secure placement of anchors having uni-directional anchor movement over the suture in a self-locking manner, various devices and methods may be utilized. Figs. 4A and 4B show side and end views, respectively, of one anchor variation **80** which is illustrated in the form of a T-type anchor. Although a T-type anchor is shown, the methods and devices used to cinch the anchor may be utilized in other types of anchors, which will be described below. Variation **80** may generally comprise an anchor body **82** having a circular, rectangular, square, etc., cross-section which defines openings **84** and **86** on opposing sides of the anchor **80**. Locking block or member **88** may be slidably disposed within anchor body **82** and define a tapered face **90** on the side of block **88** which tapers to at least one of the openings, in this case opening **86**. Openings **84**, **86** are preferably aligned with one another although this is not necessary.

[0132] Suture **94** may be routed through opening **84**, around locking block **88**, and back out through opening **86** such that when anchor body **82** is translated in the direction of arrow **96**, anchor body **82** may slide freely over suture **94** due to the manner of tapered face **90** contacting suture **84** within opening **84**. However, if anchor body **82** were translated in the opposite direction, tension within suture **94** may pull locking block **88** via suture **94** placed over contact surface **92** such that when block **88** translates in the direction of arrow **98**, suture **94** at opening **86** is forced into groove **100** defined along the leading edge of block **88**, as shown in Fig. 4B. This cleating action may effectively inhibit or prevent any further movement of anchor body **82** over suture **94**. Accordingly, anchor body **82** may be moved uni-directionally relative to suture **94** and a distally located anchor to effectively cinch tissue therebetween.

[0133] Fig. 5 illustrates another cinching anchor in the side view of anchor variation **110**. In this variation, anchor body **112** similarly defines openings **114** and **116** through which suture **96** may be routed. Locking block or member **118**, which may similarly also define tapered face **120** may be slidably disposed within anchor body **112**. Locking block **118** may

be urged via a biasing member, for instance spring **122**, to maintain a biasing force against suture **94** passing through anchor body **112**. As anchor body **112** is translated over suture **94** in the direction of arrow **96**, tapered face **120** may allow suture **94** to pass freely between openings **114**, **116**. However, if anchor body **112** were to be moved in the opposite direction, biasing member **122** may force locking block **118** to exert a force at its leading edge against suture **94**, thereby preventing its movement and allowing only uni-directional movement.

[0134] Yet another locking anchor variation **130** is shown in the side view in Fig. 6. In this variation, anchor body **132** also defines openings **134**, **136** through which suture **94** may pass. Within anchor body **132**, multiple locking blocks or members **138**, **140** may be configured to become biased in opposing directions via biasing members or springs **142**, **144**, respectively. Each of locking blocks **138**, **140** may define an opening through which suture **94** may pass. Thus, when anchor body **132** is slowly moved over suture **94** in a first direction, the anchor may translate freely. However, when moved quickly in the opposite direction, the biasing members **142**, **144** may urge their respective locking blocks **138**, **140** in directions **146**, **148** to create a tortuous path through the blocks and inhibit or prevent the reverse movement of anchor body **132** relative to suture **94**.

[0135] Fig. 7 shows a perspective view of another locking anchor variation **150** in which anchor body **152** defines an opening **154** having a tapered or grooved portion **156**. Opening **154** may be sized to allow suture **94** to pass through opening **154** such that anchor body **152** may be translated freely relative to suture **94**. Once anchor body **152** has been desirably positioned relative to the tissue fold or to the opposing anchor, suture **94** may be manipulated to slide into tapered or grooved portion **156**, which preferably defines a diameter which is less than a diameter of suture **94**. Sliding suture **94** into tapered or grooved portion **156** may lock a position of anchor body **152** relative to suture **94** due to the cleating effect of grooved portion **156** on suture **94**.

[0136] Figs. 8A and 8B show cross-sectional side and top views, respectively, of another locking anchor variation **160** in which anchor body **162** may define a through-hole passage or opening **164** through which suture **94** may pass. Anchor body **162** may have one or several levered, flapped, or biased locking members **166** which may be integrally formed with anchor body **162**. These locking members **166** may be formed radially about opening **164** such that when suture **94** is absent, the resting configuration of locking members **166** define an opening **164** having a diameter less than that of the suture **94** passed through. Locking members **166**

may be biased to protrude in a single direction, as shown in Fig. 8A, such that when anchor body **162** is moved in a first direction over suture **94**, the anchor **162** passes freely. However, when anchor body **162** is moved in the opposing direction over suture **94**, locking members **166** engage onto suture **94** and prevent any reverse translation, thereby enabling uni-directional movement and locking of anchor body **162**. Although five locking members **166** are shown, any number of members may be utilized as practicable and as desired to effect a desired degree to locking.

[0137] Fig. 8C shows a cross-sectional side view of anchor body **162** in combination with a modified suture **168** having integrated features or protrusions **170** defined along its length. Features or protrusions **170** may be defined uniformly at regular intervals along the length of suture **168** or intermittently, depending upon the desired effects, to enhance the locking ability of the anchor body onto the suture. Moreover, the features or protrusions **170** may be integrally formed protrusions or they may simply comprise knotted sections of suture. Sutures which are modified or knotted may be optionally utilized in any of the locking anchor variations as described herein in place of conventional sutures, depending upon the desired degree of locking and locking effects.

[0138] As shown in the cross-sectional views of Figs. 9A and 9B of locking anchor variations **180** and **188**, respectively, anchor body **182** may also comprise biased locking members **184**, contained within the anchor body **182**. The number and configuration of locking members **184** may be varied as desired and may optionally be apposed, as shown in Fig. 9A, or utilize a single member **184**, as shown in anchor variation **188** in Fig. 9B. The figures show knotted suture **186** used with anchor variation **180**; however, conventional sutures may also be utilized.

[0139] Fig. 9C shows another modification of suture **94** which may be utilized with any of the anchor locking variations shown herein. The portions of suture **94** which come into contact with the anchor locking mechanisms may be coated with a material having a relatively higher frictional coefficient, i.e., a coefficient of friction that is higher than the underlying suture material. For example, the portion of suture **94** may be coated with a metallic covering or slid within sleeve **181**, which may be made of a metallic material such as Titanium, Nitinol, stainless steel, etc. to enhance the locking force between suture **94** and the anchor. As shown in the figure, if sleeve **181** is utilized, the ends **183**, **185** of sleeve **181** may

be crimped onto suture **94**. One or several openings **187** may also be defined along sleeve **181** to further enhance the locking capability between suture **94** and the locking mechanism.

[0140] Aside from the use of mechanical locking features integrated within or with the anchor bodies, locking mechanisms may also utilize a variety of knotting techniques. Conventional knots, which are typically tied by the practitioner either within the body or outside the body and advanced over the suture length, may be utilized for locking the anchor in place relative to the tissue fold and opposing anchor; however, self-locking knots which enable the uni-directional travel of an anchor body relative to the suture and tissue are desirable.

[0141] Fig. 10 shows locking anchor assembly **190** with distal anchor **192**, which may be positioned distally of a tissue fold, and proximal anchor **194**, which may be positioned proximally of a tissue fold or folds. In this variation, suture **94** may be routed through proximal anchor **194** via openings **196**, **198** and extended to distal anchor **192**. At distal anchor **192**, suture **94** may be routed through opening **200** and over pin **202** positioned within distal anchor **192**. Pin **202** may function as a pulley over which suture **94** may travel during anchor locking adjustments. Suture **94** may then be routed back towards proximal anchor **194** through opening **204** and define loop **206** through which the proximal portion of suture **94** passes to thereby create a choke-type loop. The terminal end of suture **94** may then be anchored at fixed end **208** within the body of proximal anchor **194**.

[0142] In operation, when tension is applied to suture **94** or when proximal anchor **94** is advanced distally, proximal anchor **194** and distal anchor **192** may be freely drawn towards one another to secure any tissue fold or folds (not shown for clarity) disposed therebetween. However, if proximal anchor **194** were pulled or urged in the opposite direction away from the tissue or from distal anchor **192**, loop **206** would "choke" suture **94** and prevent any reverse movement of proximal anchor **194**.

[0143] Fig. 11A shows a perspective view of locking anchor assembly **210** having distal anchor **212** and proximal anchor **214** with suture **94** extending between the two anchors. Terminal end **230** of suture **94** may be knotted or otherwise retained by proximal anchor **214** and routed through opening **216** and back through opening **218** to create looped portion **228**, both openings **216**, **218** being defined in proximal anchor **214**. Suture **94** may be routed from opening **218** and through distal anchor **212** via openings **222**, **224**. Suture **94** may then be routed back to proximal anchor **214** through an opening **220** and wrapped **226** about looped

portion **228** to continue on proximally. This knotted configuration facilitates advancement of proximal anchor **214** towards distal anchor **212** but chokes suture **94** when proximal anchor **214** is moved in an opposing direction.

[0144] Figs. 11B and 11C show top and cross-sectional side views of an alternative variation on proximal anchor **214** (and distal anchor **212**, if desired). As shown, anchor **214** may optionally define grooves or channels **232** which extend at least partially between openings **216**, **218**, and **220**. These grooves or channels **232**, as seen in Fig. 11C, may be sized such that any of the overlying suture **94** are cinched or wedged into grooves **232** to facilitate the cinching action of anchor **214** with respect to suture **94**.

[0145] Another locking anchor assembly **240** is shown in the perspective view of Fig. 12A, which shows distal anchor **242** and proximal anchor **244** with suture **94** extending between the two anchors. Suture **94** may be routed through opening **246** defined through proximal anchor **244** and passed through distal anchor **242** via openings **250**, **252**. Suture **94** may then be routed back towards proximal anchor **244** and passed through opening **248** to create at least two adjacent loops (half hitch knots) **254**, **256** with looped section **258**. During cinching of proximal anchor **244** against the tissue, the knotted suture may be slid distally with proximal anchor **244**. Once proximal anchor **244** has been desirably positioned along suture **94**, the terminal end of suture **94** may be pulled, as shown by arrow **260**, to alter the knot configuration, commonly called changing the dressing of the knot, such that the knot becomes locked onto suture **94** and prevents any reverse movement of proximal anchor **244**.

[0146] Fig. 12B also shows a perspective view of another locking anchor variation similar to that shown in Fig. 12A. In this variation, suture **94** may be wrapped into two intertwined loops **264**, **266** and further wrapped again into adjacent intertwined loops **262**, **268**. Distal advancement of the knotted configuration along with proximal anchor **244** may be accomplished until the terminal end of suture **94** is placed under tension, as shown by arrow **260**. Tension may be applied once proximal anchor **244** has been desirably positioned along suture **94** to lock the knot into position and prevent any reverse movement of proximal anchor **244** along suture **94**.

[0147] Fig. 12C shows a perspective view of another anchor locking assembly similar to the variations above. The knot may be modified by wrapping suture **94** into a first set of several loops, shown as three loops **270**, **272**, **274**, although in other variations, any number of loops may be utilized depending upon the desired locking effects. Suture **94** may then be

wrapped in a second set of several additional loops in a proximally adjacent position about suture **94**, shown as loops **278**, **280**, **282** joined by looped section **276**. Likewise, any number of loops in the second set may be utilized either independent of the number of loops in the first set or to mirror the first set of loops. In either situation, once suture terminal end **284** is tightened, a knotted configuration, as shown in Fig. 12D, is formed which may be freely slid along suture **94** provided the knotted configuration itself is pushed along suture **94**, e.g., via a pusher tube, knot pusher, etc. However, once tension is applied along suture **94** by proximal anchor **244** pushing against the knot and by the tension created in the suture extending between anchors **242**, **244**, the knot locks against suture **94** and prevents reverse movement of proximal anchor **244** along suture **94**.

[0148] Fig. 12E shows a perspective view of another locking anchor variation similar to the variation shown in Fig. 12D yet having a single suture traverse between anchors **242**, **244**. In this variation, suture **94** may have terminal end **286** anchored or retained by distal anchor **242** at opening **252** and have a single suture traverse to proximal anchor **244**. A second terminal end **288** may also be anchored or retained by proximal anchor **244** at opening **246**. The portions of suture **94** extending between proximal anchor **244** and the knot may have a biasing member, e.g., spring **290**, disposed over one or both lengths of suture to maintain proximal anchor **244** and the knot under a constant force to ensure that the knot is maintained under a locking force to prevent the reverse travel of proximal anchor **244**.

[0149] Yet another variation of a locking anchor variation having a single suture traversing the anchors is shown in the perspective view of Fig. 12F. A terminal end **252** of suture **94** may be anchored or retained at distal anchor **242** and routed to proximal anchor **214** through opening **218**. The length of suture **94** may form loop **292** on a first side of proximal anchor **214** and a second loop **296** on the opposite side of proximal anchor **214** between openings **216**, **220**. Suture **94** may then be wrapped about loop **292** via loop **294** on the first side to form an interlocking suture loop. This variation is also effective in allowing proximal anchor **214** to translate over suture **94** towards the tissue and distal anchor **242** yet prevent reverse movement of proximal anchor **214** due to a choking action by the intertwined suture loops on the proximal side of proximal anchor **214**.

[0150] Fig. 12G shows a perspective view of another locking anchor variation similar to that shown in Fig. 12F. Here, suture **94** may be routed through opening **220** in proximal anchor **214** to form loop **292** before being passed through openings **218** and **216** and

intertwining loop **294** through loop **292**. Likewise, this variation is also effective in allowing proximal anchor **214** to translate over suture **94** towards the tissue and distal anchor **242** yet prevent reverse movement of proximal anchor **214**.

[0151] As mentioned above, the locking and cinching mechanisms described herein may be utilized with a variety of different anchor types. For instance, the cinching mechanisms described above may be used not only with T-type anchors but also with reconfigurable basket-type anchors. Described hereinafter are basket-type anchors configured for implantation or placement against tissue in a similar manner as described previously and examples of how cinching mechanisms may be utilized in securing tissue plications. Moreover, additional cinching mechanisms which are preferably utilizable with basket-type anchors are also described below.

[0152] When cinching or locking basket-type anchors, the baskets may be delivered into or through the tissue in the same or similar manner as described above, particularly as shown in Figs. 3A-3G. For example, Fig. 13A shows anchor delivery system **300** in proximity to tissue fold **F**. Again, tissue fold **F** may be disposed within a gastrointestinal lumen, such as the stomach, where tissue wall **W** may define the outer or serosal layer of the stomach. Delivery push tube or catheter **302** may be disposed within launch tube **18** proximally of basket anchor **306**, which is shown in a compressed delivery configuration with a relatively low profile when disposed within needle lumen **58** of needle **54**. A single basket anchor **306** is shown disposed within needle **54** only for illustrative purposes and is not intended to be limited by the number of basket anchors; rather, any number of basket anchors may be disposed within needle lumen **58** as practicable depending upon the desired procedure and anchoring results.

[0153] Suture **94** may be routed through or externally of push tube lumen **304** and further routed within and/or through proximal collar **310** of anchor **306**. The terminal end of suture **94** may be routed within anchor **306** and affixed to distal collar **308** in one variation. Alternatively, suture **94** may be affixed or anchored within anchor **306** or at proximal collar **310** depending upon the desired effect and procedure being performed. Moreover, if multiple anchors are utilized in a tissue plication procedure, suture **94** may be routed through anchor **306** such that the anchor **306** may freely slide along or over suture **94**.

[0154] The basket anchors may comprise various configurations suitable for implantation within a body lumen. Basket anchors are preferably reconfigurable from a low profile

delivery configuration to a radially expanded deployment configuration in which a number of struts, arms, or mesh elements may radially extend once released from launch tube **18** or needle **54**. Materials having shape memory or superelastic characteristics or which are biased to reconfigure when unconstrained are preferably used, e.g., spring stainless steels, Ni-Ti alloys such as Nitinol, etc. The basket anchor **306** is illustrated as having a number of reconfigurable struts or arm members **312** extending between distal collar **306** and proximal collar **310**; however, this is intended only to be illustrative and suitable basket anchors are not intended to be limited to baskets only having struts or arms. Examples of suitable anchors are further described in detail in U.S. Pat. App. Serial No. 10/612,170, which has already been incorporated herein above.

[0155] Fig. 13A shows basket anchor **306** delivered through tissue fold **F** via needle **54** and launch tube **18**. As above, the other parts of the plication assembly, such as upper and lower bail members **20**, **26**, respectively, and tissue acquisition member **28** have been omitted from these figures only for clarity.

[0156] Fig. 13B shows one variation where a single fold **F** may be secured using basket anchor **306'**. As seen, basket anchor **306'** has been urged or ejected from needle **54** and is shown in its radially expanded profile for placement against the tissue surface. In such a case, a terminal end of suture **94** may be anchored within the distal collar of anchor **306'** and routed through tissue fold **F** and through, or at least partially through, proximal anchor **318**, where suture **94** may be cinched or locked proximally of, within, or at proximal anchor **318** via any number of cinching mechanisms **316** described herein. Proximal anchor **318** is also shown in a radially expanded profile contacting tissue fold **F** along tissue contact region **314**. Locking or cinching of suture **94** proximally of proximal anchor **318** enables the adequate securement of tissue fold **F**.

[0157] If additional tissue folds are plicated for securement, distal basket anchor **306** may be disposed distally of at least one additional tissue fold **F'**, as shown in Fig. 13B, while proximal anchor **318** may be disposed proximally of tissue fold **F**. As above, suture **94** may be similarly affixed within distal anchor **306** and routed through proximal anchor **318**, where suture **94** may be cinched or locked via proximal anchor **318**, as necessary. If tissue folds **F** and **F'** are to be positioned into apposition with one another, distal basket anchor **306** and proximal anchor **318** may be approximated towards one another. As described above, proximal anchor **318** is preferably configured to allow suture **94** to pass freely therethrough

during the anchor approximation. However, proximal anchor **318** is also preferably configured to prevent or inhibit the reverse translation of suture **94** through proximal anchor **318** by enabling uni-directional travel of anchor **318** over suture **94**. This cinching feature thereby allows for the automated locking of anchors **306**, **318** relative to one another during anchor approximation.

[0158] Aside from the anchor cinching or locking mechanisms utilizing looped and knotted sutures for facilitating uni-directional locking, various mechanisms utilizing friction may also be implemented. Figs. 14A and 14B show cross-sectional side views of one variation in cinching assembly **320**. Proximal collar **322**, proximal portions of struts **312**, and distal portions of launch tube **18** are shown and other features of the assembly and tissue fold **F** have been omitted from the figure only for clarity.

[0159] A locking or cinching collar or collet **326** may be positioned within launch tube **18** proximally of anchor collar **322**. Cinching collet **326** may comprise a cylindrically shaped member defining a lumen therethrough for passage of suture **94**. A distal end of cinching collet **326** may have at least one and preferably several clamping arms or teeth **328** which are configured to cinch or clamp down upon suture **94** passing through. Proximal anchor collar **322** may be sized to correspondingly receive cinching collet **326** therewithin to create an interference fit. relative to an outer diameter of cinching collet **326**. A distal portion of anchor collar **322** may also define a tapered or angled portion **324** such that when cinching collet **326** is advanced within anchor collar **322**, angled portion **324** may effectively force clamping arms or teeth **328** to cinch radially inward upon suture **94**.

[0160] In operation, once proximal anchor **318** has been desirably positioned relative to tissue fold **F** and/or the distal anchor and with proximal collar **322** positioned within launch tube **18**, delivery push tube **302** may be advanced distally to urge cinching collet **326** into anchor collar **322** such that clamping arms or teeth **328** are clamped onto suture **94** and cinching collet **326** is friction-fitted within anchor collar **322**. Anchor collar **322** may then be urged out of launch tube **18** and the anchor left against the tissue surface.

[0161] Another cinching assembly variation **330** is shown in the cross-section view of Figs. 15A and 15C. Launch tube **18** has been omitted from these figures for clarity only. Delivery push tube **332** is shown as defining suture lumen **334** and locking member or pin lumen **336** therethrough. Although two separate lumens are shown, a single common lumen may be utilized in alternative variations. With proximal anchor collar **344** positioned distally of push

tube **332**, suture **94** may be routed through suture lumen **334** and through collar lumen **346**. Locking member or pin **338** may be positioned within lumen **336** proximally of collar lumen **326**. Fig. 15B shows an end view of push tube **332** with locking pin **338** and suture **94** positioned within prior to cinching of the anchor.

[0162] Once the anchor has been desirably positioned relative to the tissue, suture **94** may be pulled proximally such that anchor collar **344** rests against the distal end of push tube **332**. Locking pin **338**, which may define a tapered or radiused end **340** to facilitate its insertion into collar lumen **346**, may be urged distally via push rod **342** to force locking pin **338** into anchor collar **344** such that the portion of suture **94** within anchor collar **344** becomes effectively wedged and thereby prevents further movement of the anchor along suture **94**. Fig. 15C shows a cross-sectional side view of locking pin **388** having been urged into anchor collar **344** in a frictional engagement with suture **94**. Fig. 15D shows a cross-sectional end view of collar **344** with locking pin **388** and suture **94** positioned within.

[0163] Fig. 15E shows a perspective view of another cinching variation **331** which is similar to the variation described above. One or more tapered pins or blocks **339** may be slidably disposed within tapered channel **335** defined in proximal collar **333**. The figure shows two tapered pins **339**, although a single pin may be utilized or more than two pins may also be used. If two or more pins **339** are utilized, suture **94** may be passed between the pins **339**. Pins **339** may be free to slide along inner surface **337** of channel **335** in the direction of arrows **345** depending upon the direction of travel of suture **94** through channel **335**. Fig. 15F shows a perspective view of only pins **339** for clarity; as seen, pins **339** may be tapered distally from a larger diameter to a smaller diameter and although pins **339** are shown as semi-circularly shaped members, contact surface **341** may be curved or arcuate to better contact suture **94**. Moreover, contact surface **341**, which contacts suture **94** passing through channel **335**, may define a roughened surface or it may alternatively define a plurality of serrations, teeth, projections, etc., to facilitate contact against suture **94**.

[0164] In use, as proximal collar **333** is translated in the direction of arrow **343**, pins **339** may be forced proximally such that suture **94** may pass freely through channel **335**. However, if proximal collar **333** were to be translated in the opposing direction, pins **339** may be forced in the opposite direction to cinch down upon suture **94** within channel **335** and thereby inhibit any further motion.

[0165] An alternative variation of the assembly is shown in the cross-sectional views of Figs. 15G and 15H, which show a cinching anchor having a retractable pin. Fig. 15G shows proximal collar **347** with one or more retracting arms **349** extending proximally from collar **347**. Retracting arms **349** may be configured to pivot at bend **353** when urged via a compression force applied at bend **353** in the direction of arrows **355**. The application of this compression force may urge pin support collar **357** which is defined at a proximal portion of arms **349**, to move in the direction of arrow **359**. This in turn may move pin **351**, which extends from pin support collar **357**, proximally out of proximal collar **347** to thereby release suture **94** from its locked position. In one variation, retracting arms **349** may be biased to retain pin **351** within proximal collar **347** unless a compression force is applied at bend **353**.

[0166] Figs. 16A and 16B show cross-secti
assembly **350**. Cinching assembly **350** may
tubing **358** rotatingly positioned within outer
be positioned distally of outer tubing **352** an
cinching collar **374** projecting proximally fr
preferably tapered and threaded and may als
collar **368** may be rotatingly disposed upon s